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| APPLICATION NO. | FILING DATE                        | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
|-----------------|------------------------------------|----------------------|-----------------------|------------------|
| 10/579,529      | 03/06/2007                         | William G. Cance     | 5853-480-1            | 2999             |
|                 | 7590 02/27/200<br>NGELL PALMER & D | EXAMINER             |                       |                  |
| P.O. BOX 55874  |                                    |                      | HOLLERAN, ANNE L      |                  |
| BOSTON, MA      | 02205                              |                      | ART UNIT PAPER NUMBER |                  |
|                 |                                    |                      | 1643                  |                  |
|                 |                                    |                      |                       |                  |
|                 |                                    |                      | MAIL DATE             | DELIVERY MODE    |
|                 |                                    |                      | 02/27/2009            | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  | Application No.                       | Applicant(s)       |             |  |  |  |
|--|---------------------------------------|--------------------|-------------|--|--|--|
|  | 10/579,529                            | CANCE ET AL.       |             |  |  |  |
| Office Action Summary  | Examiner                              | Art Unit           |             |  |  |  |
|  | ANNE L. HOLLERAN                      | 1643               |             |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply   | ears on the cover sheet with the c    | orrespondence ad   | dress       |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |                                       |                    |             |  |  |  |
| Status   |                                       |                    |             |  |  |  |
| 1) Responsive to communication(s) filed on   |                                       |                    |             |  |  |  |
|  | · · · · · · · · · · · · · · · · · · · |                    |             |  |  |  |
| 3) Since this application is in condition for allowan  | ice except for formal matters, pro    | secution as to the | e merits is |  |  |  |
| closed in accordance with the practice under E   | x parte Quayle, 1935 C.D. 11, 45      | 3 O.G. 213.        |             |  |  |  |
| Disposition of Claims  |                                       |                    |             |  |  |  |
| 4)⊠ Claim(s) <u>1-47</u> is/are pending in the application.  |                                       |                    |             |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.   |                                       |                    |             |  |  |  |
| 5) Claim(s) is/are allowed.  |                                       |                    |             |  |  |  |
| 6)☐ Claim(s) is/are rejected.  |                                       |                    |             |  |  |  |
| 7) Claim(s) is/are objected to.  |                                       |                    |             |  |  |  |
| 8) Claim(s) <u>1-47</u> are subject to restriction and/or e  | election requirement.                 |                    |             |  |  |  |
| Application Papers   |                                       |                    |             |  |  |  |
| 9) ☐ The specification is objected to by the Examiner.   |                                       |                    |             |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.   |                                       |                    |             |  |  |  |
| Applicant may not request that any objection to the o  |                                       |                    |             |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |                                       |                    |             |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |                                       |                    |             |  |  |  |
| Priority under 35 U.S.C. § 119   |                                       |                    |             |  |  |  |
| 12) Acknowledgment is made of a claim for foreign  | priority under 35 LLS C. 8 119(a)     | -(d) or (f)        |             |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:   | priority under 30 0.0.0. § 113(a)     | -(a) or (i).       |             |  |  |  |
| 1. Certified copies of the priority documents  | s have been received.                 |                    |             |  |  |  |
| 2. Certified copies of the priority documents  |                                       | on No              |             |  |  |  |
| 3. ☐ Copies of the certified copies of the prior   |                                       |                    | Stage       |  |  |  |
| application from the International Bureau  | •                                     |                    | o .         |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |                                       |                    |             |  |  |  |
|  |                                       |                    |             |  |  |  |
| Attachment(s)  |                                       |                    |             |  |  |  |
| 1) X Notice of References Cited (PTO-892)  | 4) Interview Summary                  | (PTO-413)          |             |  |  |  |
| 2) DNotice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Da                   | ite                |             |  |  |  |
| 3) Information Disclosure Statement(s) (PTO/SB/08)   | 5)  Notice of Informal P 6)  Other:   | atent Application  |             |  |  |  |
| Paper No(s)/Mail Date  | o) 🔲 Other                            |                    |             |  |  |  |

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## **DETAILED ACTION**

## Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 6-11, and 18-22, drawn to agents, or compositions comprising agents that specifically bind focal adhesion kinase and induce apoptosis in a cell that expressed focal adhesion kinase.

Group II, claim(s) 4, 5, 12-17 and 32-47, drawn to methods of inducing apoptosis or methods of treating cancer, comprising contacting a cell or administering to a patient, an agent or a composition comprising an agent that binds focal adhesion kinase.

Group III, claim(s) 23-31, drawn to vectors expression amino acids as identified by SEQ ID NO: 1 and/or SEQ ID NO: 3, derivatives, fragments and variants thereof.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the feature that is common to groups I-III is an agent that binds focal adhesion kinase is not a special technical feature because peptides and antibodies that bind to focal adhesion kinase and induce apoptosis are known in the art as evidenced by Hungerford (Hungerford, J.E. et al, The Journal of Cell Biology, 135(5): 1383-1390, 1996). Hungerford teaches, separately a peptide and an antibody that each binds to focal adhesion kinase and causes cells to apoptose (see abstract; pages 1384-1386). Thus, an agent that binds to focal adhesion kinase and induces apoptosis is not a feature that makes a contribution over the prior art as a whole. Therefore, the feature that is common to groups I-III is cannot be considered a special technical feature.

The technical feature of group I is that of an agent the binds focal adhesion kinase and induces apoptosis in a cells that expresses focal adhesion kinase.

The technical feature of group II is that of a method comprising contacting either in vitro or in vivo a cancer cell with an agent that binds to focal adhesion kinase.

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The technical feature of group III is that of a vector that comprises a nucleic acid encoding the amino acid sequence of SEQ ID NO: 1 and/or SEQ ID NO: 3.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

## In re Ochiai:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. <u>All</u> claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

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Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran Patent Examiner February 23, 2009 /Alana M. Harris, Ph.D./ Primary Examiner, Art Unit 1643